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Office of Regulatory Policy  
HFD-7  
5600 Fishers Lane (Rockwall II Rm 1101)  
Rockville, MD 20857


Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 4,911,932 was filed on April 5, 2006, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Vusion™, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, we note that miconazole nitrate has been previously reviewed under section 505(b) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)) and was approved for marketing and use in several products before the approval of Vusion™. Please confirm that the approval of Vusion™, i.e., the other active ingredients of Vusion™, were subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use.

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

  
Kery A. Fries  
Senior Legal Advisor  
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